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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,130	09/10/2003	Christopher Patrick Lawson	GJ-246J	3558

7590 08/09/2006
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EXAMINER	
NATNITHADHA, NAVIN	
ART UNIT	PAPER NUMBER
3735	

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/659,130	Applicant(s) LAWSON, CHRISTOPHER PATRICK	
	Examiner Navin Natnithithadha	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some * c) ☐ None of:
 - 1. ☒ Certified copies of the priority documents have been received.
 - 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Claims 1 and 2 have been amended. Claims 1-13 are pending.
2. New corrected drawings in compliance with 37 CFR 1.121(d) have been received.
3. The objections to Specification are WITHDRAWN in view of the Amendment.
4. The objections to claims 1 and 2 are WITHDRAWN in view of the Amendment.
5. Applicant's arguments, see Remarks, on page 11, lines 6-9, filed 05 June 2006, with respect to claims 3-13 have been fully considered and are persuasive. The objection of claims 3-13 has been withdrawn.

Examiner's Comments

6. The Examiner suggests amending claim 1 as follows to more clearly define the structure of the apparatus:

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1. Apparatus for measuring the strength of a person's respiratory muscles, ~~which~~ the apparatus comprising:

a mouthpiece for the person;

a flow transducer;

a variable orifice valve;

a motor for operating the variable orifice valve; and

a microprocessor controller;

wherein the microprocessor controller ~~being such that it~~ controls the motor to cause the variable orifice valve to vary its orifice size in response to at least one of flow and pressure signals obtained consequent upon the person breathing into the mouthpiece,

wherebyin the orifice size maintains a constant predetermined pressure and enables measurement of the flow rate generated by the person, or the orifice size maintains a constant predetermined flow rate and enables measurement of the pressure generated by the person.

- - .

Specification

7. The amendment filed 05 June 2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "in response to at least one of flow and pressure signals obtained consequent upon the person breathing into the mouthpiece" (see Amendment, pp. 2, 3, and 5).

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claim 1, lines 7-9, the limitation “in response to at least one of flow and pressure signals obtained consequent upon the person breathing into the mouthpiece” was not properly described in the application as filed, and is considered new matter. Thus, it is not clear as to whether the Applicant had possession of the claimed invention as amended on 05 June 2006. Nowhere in the disclosure as filed described or suggested that the microprocessor controller controls the motor to cause the variable orifice valve to vary its orifice size in response to at least one of flow and pressure signals.

Response to Arguments

9. Applicant's arguments filed 05 June 2006 have been fully considered but they are not persuasive.

On pages 11-12 of the Applicant's Remarks, filed on 05 June 2006, the Applicant argues that “[t]hus the Jiang valve controller 5 is not as required by the Applicant's amended claim 1, i.e. the Jiang valve controller 5 is not able to vary the orifice size of

the Jiang valve 4 in response to at least one of flow and pressure signals obtained consequent upon the person breathing into the mouthpiece, whereby the orifice size maintains a constant predetermined pressure and enables measurement of the flow rate generated by the person, or the orifice size maintains a constant predetermined flow rate and enables measurement of the pressure generated by the person."

However, the amended limitation "in response to at least one of flow and pressure signals obtained consequent upon the person breathing into the mouthpiece" is considered new matter. Thus, it is not clear as to whether the Applicant had possession of the claimed invention as amended. The Examiner will interpret claim (excluding new matter) to describe that the microprocessor controller being such that it controls the motor to cause the variable orifice valve to vary its orifice size, whereby the orifice size maintains a constant predetermined pressure and enables measurement of the flow rate generated by the person, or the orifice size maintains a constant predetermined flow rate and enables measurement of the pressure generated by the person.

Jiang's valve controller 5 controls the motor (see col. 5, lines 13-14) to cause the variable orifice valve to vary its orifice size (see col. 9, lines 32-36), which results in a constant predetermined pressure in mouthpiece (pipe) 1 and enables measurement of the flow rate or pressure generated by the person. Since Jiang anticipates the structure of claim 1 (excluding new matter), the 35 U.S.C. 102(b) rejection of claims 1-4, 6, and 13 is MAINTAINED.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims 1-4, 6, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Jiang et al, US 6,030,350 A (hereinafter referred to as Jiang).

Claim 1: Jiang teaches an apparatus (see fig. 2), comprising: a mouthpiece 2; a flow transducer 11 (see col. 9, lines 60-61); a pressure transducer 7 (see col. 10, lines 13-14); a variable orifice valve (shutter valve) 4 controlled by a motor (see col. 5, lines 63-65); and a microprocessor controller (valve controller) 5. See *Response to Arguments* above.

Claim 2: Jiang teaches the pneumatic and electrical interconnections of the flow transducer 11, pressure transducer 7, control circuit (valve controller) 5, and microprocessor control means 16.

Claims 3 and 4: Jiang teaches the microprocessor control means 16 as a standard personal computer including a circuit, display means (display screen), and a keypad (see fig. 2).

Claims 6 and 13: Jiang teaches a rotary or flat plate variable orifice valve 4 as a shutter type valve (see col. 5, lines 63-65).

11. Claims 1, 2, and 6-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Holscher, US 6,630,411 A (hereinafter referred to as Holscher).

Claims 1, 2, and 6-12: Holscher teaches an apparatus (see fig. 1), comprising: a mouthpiece (inlet tube) 20/130; a flow transducer 18; a pressure transducer 16; a rotary

variable orifice valve 14, which comprises an triangular shaped orifice, a cylindrical member and a sleeve; a motor 78 (see fig. 5); and a microprocessor controller 26, the microprocessor controller 26 being connected to the pressure transducer 16 and flow transducer 18.

12. Claims 1-4 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Hillsman, WO 98/14115 A (hereinafter referred to as Hillsman).

Claims 1-4 and 13: Hillsman teaches an apparatus (see fig. 2), comprising: a mouthpiece (not labeled); a flow transducer 4; a pressure transducer 5; a flat plate or rotary variable orifice valve 3 (see figs. 3A, 3B, 3C); a motor 28; a display 6 and a microprocessor controller (computer) 14, the microprocessor controller 14 being connected to the pressure transducer 5 and flow transducer 4. Although not disclosed in Hillsman, it is well known in the art that a keypad/keyboard and microprocessor circuit would be connected to or included within the "computer" 14.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

13. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jiang et al, US 6,030,350 A, as applied to claim 1 above, and further in view of either Bacaner et al, US 4,966,141 (hereinafter referred to as Bacaner).

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Claim 5: Jiang does not teach the mouthpiece has a flange. However, Bacaner teaches a disposable mouthpiece 200 including a flange 203 (see fig. 19 and col. 19, lines 52-53). Thus, it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Jiang's mouthpiece to include flange as taught by Bacaner in order to provide a disposable mouthpiece that effectively engages the face of the patient surrounding the mouth (see Bacaner, col. 19, lines 55-57).

14. Claims 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jiang et al, US 6,030,350 A, as applied to claim 6 above.

Claims 7-12: Jiang teaches using many suitable valves and valve controllers are known and available, such a balloon valve or shutter valve which can be opened and closed by a motor (see col. 5, lines 58-65). Jiang does not explicitly teach the type of valve structures in claims 7-12. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the valve structures claimed because Applicant has not disclosed that these valve structures provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with a balloon valve or shutter valve because Jiang states that these valves are suitable valves for obstructing airflow (see col. 5, lines 39-65). Therefore, it would have been obvious matter of design choice to modify Jiang to have a valve assembly 4 as specified in claims 7-12.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Navin Natnithithadha whose telephone number is (571) 272-4732. The examiner can normally be reached on Monday-Friday, 8:00-4:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Navin Natnithithadha
Patent Examiner – GAU 3735
01 August 2006



Charles A. Manner, II
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